K140455

MAY 2 2 2014

Trinity Biotech Captia™ Measles IgM 510(k) Summary

Trinity Biotech hereby submits this 510(k) summary for the Captia™ Measles IgM Test in accordance with the requirements of 21CFR 807.92(C)

Submitter's Identification:

Name & Address Trinity Biotech
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A. 510(k) Number:

K140455

B. Purpose for Submission:

Traditional 510(k) in accordance with the requirements of 21CFR 807.92(C)

C. Measurand:

Measles-specific IgM antibodies in human serum

D. Type of Test:

Enzyme-Linked Immunosorbent Assay (ELISA)

E. Applicant:

Trinity Biotech

F. Proprietary and Established Names:

Captia™ Measles IgM

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3520 Rubeola (measles) virus serological reagents

2. Classification:

   Class I

3. Product code:

   PCL

4. Panel:

   83 (Microbiology)

H. Intended Use:

1. Intended use(s):

   The Trinity Biotech Captia™ Measles IgM Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative detection of Measles IgM antibodies in human serum of patients suspected of measles (rubeola) infection. This assay is intended for use as an aid in the diagnosis of a current or recent measles (rubeola) infection in conjunction with other clinical information and laboratory findings.

   Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. This test is not intended for use in neonatal screening or for use at a point of care. This test is not intended for use in screening blood and plasma donors.

2. Indication(s) for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Not applicable

I. Device Description:

The Trinity Biotech Captia™ Measles IgM test is an Enzyme-Linked Immunosorbent Assays (ELISA). When measles antigen (Edmonston strain) is bound to the solid phase and brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgM globulin conjugated with horseradish peroxidase which will bind to the antibody-antigen

complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H_2SO_4, The contents of the wells turn yellow. The color, which is indicative of the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on the package label.

1. Purified measles antigen coated microassay plate: 96 wells, configured in twelve 1x8 strips stored in a foil pouch with desiccant. (96T: one plate)
2. Calibrator: Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with kit specific factor printed on vial label. The Calibrator is used to calibrate the assay to account for day-to-day fluctuations in temperature and other testing conditions. (96T: one vial, 0.4 mL) *
3. Positive Control: Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with established range printed on vial label. The Positive Control is utilized to control the positive range of the assay.(96T:one vial, 0.4 mL) *
4. Negative Control: Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with established range printed on vial label. The Negative Control is utilized to control the negative range of the assay (96T: one vial, 0.4 mL) *
5. Horseradish-peroxidase (HRP) Conjugate: Ready to use. Goat anti-human IgM, containing ProClin® (0.1%) and gentamicin as preservatives. (96T: one bottle, 16 mL)
6. Serum Diluent Plus: Ready to use, Contains goat/sheep anti-human IgG for serum absorption to remove competing IgG, with protein stabilizers and ProClin® (0.1%) as a preservative. (96T: two bottles, 45 mL each)
7. Wash Buffer Type I (20X concentrate): dilute 1 part concentrate + 19 parts deionized or distilled water. Contains TBS, Tween-20 and ProClin® (0.1%) as a preservative. (96T: one bottle, 50 mL)
8. Chromogen/Substrate Solution Type I: Tetramethylbenzidine (TMB), ready to use. The reagent should remain closed when not in use. If allowed to evaporate, a precipitate may form in the reagent wells. (96T: one bottle, 15 mL)
9. Stop Solution: Ready to use, contains a 1N H_2SO_4 solution. (96T: one bottle, 15 mL)
10. Package Insert

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Gull Rubeola IgM ELISA kit

2. Predicate 510(k) number(s):

   K904083

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The Trinity Biotech Captia™ Measles IgM Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative detection of Measles IgM antibodies in human serum of patients suspected of measles (rubeola) infection. This assay is intended for use as an aid in the diagnosis of a current or recent measles (rubeola) infection in conjunction with other clinical information and laboratory findings. Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. This test is not intended for use in neonatal screening or for use at a point of care. This test is not intended for use in screening blood and plasma donors.	The Gull Rubeola igM ELISA test is intended for the qualitative detection of IgM antibody to rubeola (measles) virus in human serum. When performed according to the instructions, the Rubeola IgM ELISA test is of value in the determination of recent exposure to and infection with rubeola virus and in the diagnosis of rubeola virus-associated disease.
Technology	Enzyme-Linked Immunosorbent Assay (ELISA)	Same
Specimen Types	Human Serum	Same

Differences		
Item	Device	Predicate

K. Standard/Guidance Document Referenced (if applicable):

- CLSI EP7-A2 Interference in Clinical Chemistry
- CLSI H18-A4 Procedures for Handling & Processing Blood Specimens
- CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods
- CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance

L. Test Principle:

The Trinity Biotech Captia™ Measles IgM test is an Enzyme-Linked Immunosorbent Assays (ELISA). When measles antigen (Edmonston strain) is bound to the solid phase and brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgM globulin conjugated with horseradish peroxidase which will bind to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H_2SO_4, The contents of the wells turn yellow. The color, which is indicative of the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. High Dose Hook Effect:

When antigen is evaluated for purchase, it is titrated to ensure there is no dose hook effect (prozone) of antigen on the plate. If prozoning is apparent then the antigen is titrated out further past the prozone point.

Due to the nature of obtaining IgM positive serum in general, positive serum purchased for the Captia Measles IgM generally contains less antibody than would be present to demonstrate dose hook effect (prozone), although the positive control in each kit lot is titrated to negative at each kit QC test stage to ensure the positive control is not prozoning.

b. IgM/IgG Competition:

Specific IgG may compete with the IgM for sites and may result in a false negative. Conversely, rheumatoid factor in the presence of specific IgG may result in a false positive reaction. The Serum Diluent Plus Solution diminishes competing virus-specific IgG and minimizes rheumatoid factor interference in samples. Studies indicate that the maximum amount of IgG which can be removed by the kit Serum Diluent Plus is in excess of the expected high end of the normal range for IgG > 1380 mg/dL. The highest titer of RF+ tested (1: 1280; 500 IU/mL) did not adversely affect the performance of the assay.

c. *Precision/Reproducibility:*

The Trinity Biotech Captia™ Measles IgM ELISA Test Kit was evaluated for inter-assay precision. This study consisted of six (6) blinded proficiency panel members, varying in reactivity: Four (4) low to moderate Positive samples and two (2) Negative samples run in triplicate at three (3) separate facilities. Testing at each site was done over 10 days by two (2) operators at each site resulting in a total number of 180 data points. The results are summarized below:

Precision Between All Sites.

Sample ID	ISR Site 1 N=60	ISR Site 2 N=60	ISR Site 3 N=60	MEAN	STD DEV	% CV
1	1.30	1.34	1.23	1.29	0.055678	4.3%
2	0.57	0.68	0.67	0.64	0.060828	9.5%
3	1.16	1.26	1.07	1.16	0.095044	8.2%
4	1.92	1.84	1.76	1.84	0.08000	4.3%
5	0.67	0.82	0.84	0.78	0.092916	12.0%
6	1.28	1.18	1.01	1.16	0.136504	11.8%

The Trinity Biotech Captia™ Measles IgM ELISA Test Kit was evaluated for lot to lot precision. This study consisted of six (6) blinded proficiency panel members, varying in reactivity: four (4) low to Moderate Positive samples and two (2) Negative samples run in triplicate on three (3) separately manufactured kit lots. The results are summarized below:

Inter-lot Reproducibility

Sample ID	ISR's Lot 1	ISR's Lot 2	ISR's Lot 3	Mean	Std Dev	% CV
1	1.22	1.43	1.36	1.34	0.120773	9.02
2	0.57	0.42	0.46	0.48	0.108972	22.55
3	1.19	1.31	1.24	1.25	0.103253	8.27
4	2.13	1.96	1.56	1.88	0.27924	14.83
5	0.79	0.75	0.56	0.7	0.109545	15.72
6	1.27	1.32	1.3	1.29	0.041265	3.19

A separate precision/reproducibility study was performed internally (Trinity Biotech, Jamestown) using one (1) lot of the Captia™ Measles IgM ELISA Test Kit. The study compared the consistency between two (2) Operators. This study consisted of six (6) blinded proficiency panel members, varying in reactivity: Four (4) Low to

moderate Positive samples, and two (2) Negative samples run by each of the Operators over 10 days. The results are summarized below:

Intra-run Precision/Reproducibility Between users:
Total Precision at Site 1 with Two Operators Over Ten Days

Sample ID	ISR's Operator 1 N=30	ISR's Operator 2 N=30	MEAN ISR	STD DEV	% CV
1	1.26	1.33	1.3	0.0495	3.80%
2	0.58	0.55	0.57	0.02121	3.80%
3	1.14	1.17	1.16	0.02121	1.80%
4	1.92	1.91	1.92	0.00707	0.40%
5	0.69	0.65	0.67	0.02828	4.20%
6	1.32	1.23	1.28	0.06364	5.00%

d. Linearity/assay reportable range:

Not Applicable

e. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability – The Controls and Calibrators are traceable against frozen internal Quality Control standard panels. The panels consist of patient samples whose values span the assay range.

Stability – Real time stability studies support the shelf life of the Reagents, Controls and Calibrators at 2 – 8° C up to the stated expiration date on the labeling.

Expected Values – The ISR (Immune Status Ratio) Values for the Positive and Negative Controls should be in their respective ranges printed on the vial labels. If the Control values are not within their respective ranges, the test should be considered invalid and should be repeated.

f. Detection limit:

Not Applicable

g. Analytical specificity:

Cross Reactivity

47 samples were used for establishing the potential cross reactivity of the Trinity Biotech Captia™ Measles IgM ELISA Test Kit. The samples were selected as confirmed positive by Trinity Biotech Captia™ CMV IgM, HSV1 IgM, HSV2 IgM, Rubella IgM, VZV IgM and

Mumps IgM test kits, for each of the following potentially cross-reacting agents: CMV, HSV-1, HSV-2, Rubella, VZV, Mumps and Parvo-B19. Fourteen (14) of the suspected cross reactive samples tested as measles IgM antibody tested positive or equivocal (12 positive and 2 equivocal) with the Trinity Biotech Captia™ Measles IgM ELISA test kit. These 14 samples were then run on a comparator Measles IgM IFA test kit and a comparator Measles IgM ELISA test kit. A sample was determined as measles IgM antibody positive if the results on two (2) measles IgM tests were positive. A sample was determined as measles IgM antibody negative if the results on two (2) measles IgM tests were negative. The results are presented in the table below:

Cross Reacting Agents	**Number of Samples**	**Trinity Biotech Captia™ Measles IgM Result**				**Consensus Comparator Result***	
		Neg	Pos	Equiv		Neg	Pos
Mumps IgM	4	4	0	0		NT	NT
VZV IgM	4	4	0	0		NT	NT
Rubella IgM	4	4	0	0		NT	NT
CMV IgM	7	3	3	1		3	1
HSV1 IgM	16	9	7	0		5	2
HSV 2 IgM	10	7	2	1		2	1

NT = Not tested

* Tested only if Captia™ Measles IgM result was positive.

Potential cross reactivity was observed with CMV IgM, HSV1 and HSV2 IgM. Potential cross-reactivity with Parvovirus, Respiratory Syncytial Virus (RSV) and parainfluenza has not been ruled out, as either specimens were not tested or a limited number were tested.

Interfering Substances

Interfering substance testing was conducted using three (3) characterized samples for measles IgM, spiked with recommended interfering substances according to the guidance in the CLSI document EP7-A2 (Interference Testing in Clinical Chemistry; Approved Guideline 2nd Ed). Results from the three (3) samples tested as spiked with the interfering substance and unspiked (as a control) were favourable. No adverse results or significant change in results occurred with these samples tested with the following:

Potential Interferent	**Concentration**
Hemoglobin	≥500 mg/dL
Bilirubin (unconjugated)	≥20 mg/dL

Interference with substances such as red cells, cholesterol, gamma globulin, triglycerides, beta carotene, protein, ascorbic acid and anticoagulants have not been tested.

h. Assay cut-off:

The objective of this study was to demonstrate the performance of the Trinity Biotech Captia™ Measles IgM ELISA Test Kit; specifically to generate data to demonstrate determination of the cut-off. The results are summarized below:

228 Measles IgM negative sera were assayed on the Trinity Biotech Captia™ Measles IgM ELISA Test Kit. Four (4) samples were disqualified as they were in the equivocal range on Trinity IgM ELISA or indeterminate on a comparator Measles IFA test kit (due to non-specific staining most likely due presences of ANA antibodies). The mean and standard deviation of the optical density readings for the sera were 0.105 and 0.070 respectively. The positive threshold for the assay was determined by adding the mean and 4 standard deviations (0.105 + 4(0.070) = 0.385). Positive sera were titrated to give a constant ratio of the threshold value to obtain a Cut-off Calibrator serum. On all subsequent assays, this serum was run and the assay was calibrated by multiplying the OD value for the calibrator by the ratio to the cut-off to obtain the cut-off calibrator value. This value was then divided into the O.D. for the patient sera to obtain an Immune Status Ratio (ISR). By definition the Cut-off ISR is equal to 1.00. To account for inherent variation in immunoassay, values of 0.91 to 1.09 were considered equivocal. Therefore values ≤ 0.90 are considered negative and values ≥ 1.10 are considered positive.

i. Seroconversion study:

The BIOMEX Rubeola IgG and IgM Antibody Seroconversion Panel (Cat No. SCP-MEA-001) contained 15 samples depicting the onset and decline of IgG and IgM antibodies to Rubeloa (Measles) from one individual over a period of 55 days. The 15 member panel demonstrated an IgM response consistent with an antibody response for seroconversion when tested on four (4) different lots of the Trinity Biotech Captia™ Measles IgM ELISA Test Kit.

The seroconversion panel consisted of one patient with 15 draws during an approximately two month period from May 31st to July 25th, 1994. Seroconversion was demonstrated at Day 20 on the Trinity Biotech Captia™ Measles IgM ELISA Test Kit, and remained positive until Day 22Comparator 1 demonstrated seroconversion at Day 22 and was positive only at that bleed date. Comparator 2 sero-conversion happened earlier than the Trinity kit by 2 days and remained positive for the remainder of timeframe. The results are summarized below:

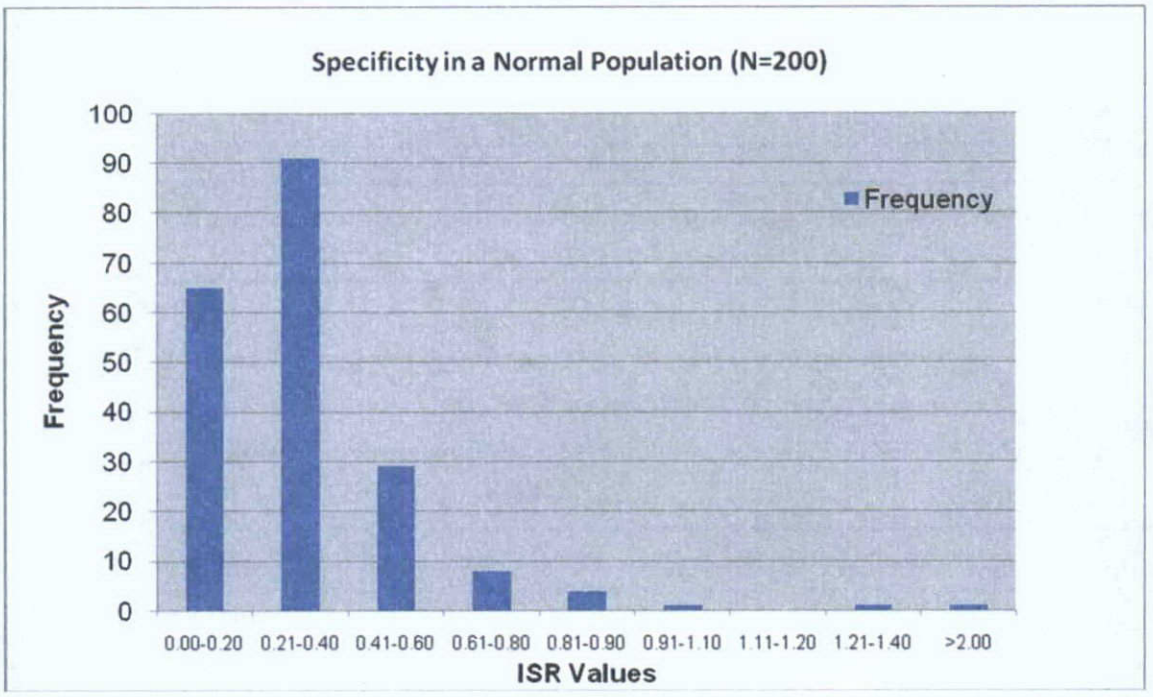
	Trinity Biotech Captia™ Measles IgM ELISA								Comparator 1		Comparator 2	
	Lot 027		Lot 28		Lot 29		Lot 030		Rubeola IgM		Rubeola IgM	
Bleed Day	ISR	Result	ISR	Result	ISR	Result	ISR	Result	S/CO	Result	S/CO	Result
Day1	0.22	Neg	0.29	Neg	0.2	Neg	0.12	Neg	NT	NT	0.429	Neg
Day 6	0.29	Neg	0.33	Neg	0.24	Neg	0.15	Neg	0.02	Neg	0.449	Neg
Day 8	0.25	Neg	0.31	Neg	0.21	Neg	0.14	Neg	-0.04	Neg	0.389	Neg
Day 13	0.26	Neg	0.34	Neg	0.27	Neg	0.21	Neg	0.28	Neg	1.101	Pos
Day 15	0.44	Neg	0.51	Neg	0.54	Neg	0.43	Neg	0.46	Neg	3.045	Pos
Day 20	1.53	Pos	1.71	Pos	1.77	Pos	1.28	Pos	0.92	Neg	7.332	Pos
Day 22	1.36	Pos	1.4	Pos	1.49	Pos	1.24	Pos	1.09	Pos	5.919	Pos
Day 27	0.84	Neg	*0.92*	equiv	*0.96*	equiv	0.71	Neg	0.5	Neg	3.785	Pos
Day 29	0.59	Neg	0.8	Neg	0.89	Neg	0.54	Neg	0.33	Neg	3.296	Pos
Day 35	0.54	Neg	0.63	Neg	0.62	Neg	0.47	Neg	0.61	Neg	2.449	Pos
Day 37	0.44	Neg	0.53	Neg	0.53	Neg	0.79	Neg	0.24	Neg	2.113	Pos
Day 43	0.44	Neg	0.6	Neg	0.54	Neg	0.38	Neg	0.17	Neg	2.04	Pos
Day 45	0.37	Neg	0.5	Neg	0.5	Neg	0.31	Neg	0.15	Neg	1.802	Pos
Day 49	0.34	Neg	0.59	Neg	0.39	Neg	0.28	Neg	0.04	Neg	1.471	Pos
Day 54	0.38	Neg	0.5	Neg	0.42	Neg	0.29	Neg	0.27	Neg	1.47	Pos

j. Specificity in a Normal Population

A total of 200 random serum samples were tested to establish the expected values in a population of individuals between the ages 18-65 with no known clinically apparent Measles infection. The table below summarizes the distribution of Trinity Biotech Measles IgM assay ISR Values observed for the population.

Distribution of Trinity Biotech Captia™ Measles IgM Assay ISR Values from a Normal Population

Measles IgM ISR Range	Number of Specimens (Frequency)	Percent of Total
0.00-0.20	65	32.5%
0.21-0.40	91	45.5%
0.41-0.60	29	14.5%
0.61-0.80	8	4.0%
0.81-0.90	4	2.0%
0.91-1.10	1	0.5%
1.11-1.20	0	0.0%
1.21-1.40	1	0.5%
>2.00	1	0.5%



2. Comparison studies:

   a. *Method comparison with predicate device:*

      See Clinical Studies.

   b. *Matrix comparison:*

      Not Applicable. The kit is for use with Human Serum only.

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Not Applicable

   b. *Clinical specificity:*

      Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

Three (3) studies were conducted to evaluate the performance of the Trinity Biotech Captia™ Measles IgM ELISA test kit.

Studies 1 and 2

188 samples were collected from individuals in whom a measles IgM test was ordered (suspected of measles infection in outbreak settings by the Texas Department of Health, Austin, Texas (66 samples) and the State Laboratory of Public Health in Raleigh, North Carolina (122 samples)). All serum samples were tested on the Trinity Biotech Captia™ Measles IgM ELISA test kit. All but one (1) sample was tested by a comparator testing algorithm used at each institution to determine the presence of current or recent measles infection, referred to as "comparator algorithm" in the performance tables. The algorithms used consisted of the results of other laboratory confirmation methods including comparator Measles IgM ELISA test kit, a comparator Measles IgM IFA test kit, Complement Fixation (CF), Hemagglutionation Inhibition (HI) and the Trinity Biotech Captia™ Measles ELISA IgG test kit. See Table below for results.

		Comparator Algorithm		
		+	Indeterminate	-
Trinity Biotech Captia™ Measles IgM	+	88	1	6
	Equivocal	3	3	10
	-	5	1	70

	# Agree	Total	Result	95% CI
% Positive Agreement	88	96	91.67%	84.2-96.3
% Negative Agreement	70	86	81.40%	71.6-89.0

Percent of Captia™ Measles IgM Results that are Equivocal = 8.6% (16 of 187)

Performance with the indeterminate results from the comparator algorithm calculated against the performance of the Captia™ Measles IgM:

		Comparator Algorithm		
		+	Indeterminate	-
Trinity Biotech Captia™ Measles IgM	+	88	1	6
	Equivocal	3	3	10
	-	5	1	70

	# Agree	Total	Result	95% CI
% Positive Agreement	88	97	90.7%	83.3-95.0%
% Negative Agreement	70	87	80.5%	70.9-87.4%

Percent of Captia™ Measles IgM Results that are Equivocal = 8.6% (16 of 187)

Study 3

Eight (8) samples were submitted for testing at the Kansas Department of Health and Environment Laboratory (KDHE), Topeka, Kansas. All samples were tested on the Captia™ Measles IgM and Captia™ Measles IgG ELISA test kits as well ascompared to the method used by the testing institution to determine the presence of current or recent measles infection, referred to as "comparator algorithm" in the performance table. The comparator algorithm included RNA polymerase chain reaction (PCR) on urine, nasopharyngeal swab (NPS) and/or throat swab (TS) samples. The final % agreement is presented in the table below:

		Comparator Algorithm		
		+	Indeterminate	-
Trinity Biotech Captia™ Measles IgM	+	3	0	0
	Equivocal	0	0	0
	-	0	1*	4

	# Agree	Total	Result	95% CI
% Positive Agreement	3	3	100.00%	29.2-100.0%
% Negative Agreement	4	4	100.00%	39.8-100.0%

- This sample tested NPS negative at two sites, urine positive at one site and urine indeterminate at one site (all testing done by PCR).

Performance with the indeterminate results from the comparator algorithm calculated against the performance of the Captia™ Measles IgM:

		Comparator Algorithm		
		+	Indeterminate	-
Trinity Biotech Captia™ Measles IgM	+	3	0	0
	Equivocal	0	0	0
	-	0	1*	4

	# Agree	Total	Result	95% CI
% Positive Agreement	3	4	75.00%	30.1-95.4%
% Negative Agreement	4	4	100.00%	39.8-100.0%

4. Clinical cut-off:

Refer to Assay Cut-off above.

5. Expected values/Reference range:

IgM antibodies appear in the first week of infection and usually peak within a month. Although uncommon, low levels of IgM may persist for one (1) year or longer. The annual incidence rates are reported to vary in different geographical areas.

Recent reports (2004-2011) from the Centers for Disease Control and Prevention (CDC) indicate that annual measles incidence is <1 reported case per 1 million population. A large proportion of cases (40%) are international imported or associated with importation. Unknown source cases are not linked to any endemic chain (12%). Most imported cases do not lead to spread in the United States. This is attributed to high levels of vaccination coverage (CDC Report: Documentation and Verification of Measles, Rubella and Congenital Rubella Syndrome Elimination in the Region of the Americas, United States National Report, CDC March 28, 2012).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TRINITY BIOTECH
BONNIE B. DEJOY
2823 GIRTS RD
JAMESTOWN, NY 14701

May 22, 2014

Re: K140455
Trade/Device Name: Captia™ Measles IgM
Regulation Number: 21 CFR 866.3520
Regulation Name: Rubeola (measles) virus serological reagents
Regulatory Class: I
Product Code: PCL
Dated: February 21, 2014
Received: February 24, 2014

Dear Ms. DeJoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Sally A. Hojvat M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140455

Device Name
Captia™ Measles IgM ELISA

Indications for Use *(Describe)*

The Trinity Biotech Captia™ Measles IgM Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative detection of Measles IgM antibodies in human serum of patients suspected of measles (rubeola) infection. This assay is intended for use as an aid in the diagnosis of a current or recent measles (rubeola) infection in conjunction with other clinical information and laboratory findings.

Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. This test is not intended for use in neonatal screening or for use at a point of care. This test is not intended for use in screening blood and plasma donors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stephen J. Lovell -S
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